

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant :	Jan Andersson <i>et al.</i>	Art Unit :	3743
Serial No. :	10/673,689	Examiner :	Jasveer Singh
Filed :	September 29, 2003	Conf. No. :	1299
Title :	INHALATION DEVICE		

**Mail Stop Appeal Brief - Patents**

Commissioner for Patents

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BRIEF ON APPEAL

Appellants are appealing the final rejection of claims 34-41 and 55-64 in the Office Action dated May 15, 2006, and the Advisory Action dated November 1, 2006. A Notice of Appeal was filed and received by the U.S. Patent and Trademark Office on November 9, 2006.

**(i) Real Party in Interest**

The Real Party in Interest is AstraZeneca AB, the assignee of record, which is a subsidiary of AstraZeneca PLC.

**(ii) Related Appeals and Interferences**

There are no prior or pending related appeals, judicial proceedings, or interferences.

**(iii) Status of Claims**

Claims 1-33 and 42-54 are canceled.

Claims 34-41 and 55-64 are rejected and under appeal.

**(iv) Status of Amendments**

All previously filed amendments have been entered. No amendments are being submitted herewith.

**(v) Summary of Claimed Subject Matter**

The claims are directed to a powder inhaler for administering powder by inhalation. Claims 34 and 35 are the independent claims.

The powder inhaler of **independent claim 34** includes a dosing unit for providing a dose of powder, and a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is drawn on inhalation by a user. The powder inhaler is characterized in that at least one of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path. The inhaler also includes a powder dislodging member which is fixed in position relative to one of the at least one surface or at least one other of the surfaces of the flow path. The powder dislodging member is also configured such that on relative movement of the at least one surface and at least one other of the surfaces of the flow path, the powder dislodging member contacts the other of the at least one surface or at least one other of the surfaces of the flow path such as to dislodge powder accumulated on the surface. The powder dislodging member includes a scraper or a brush. Support for independent claim 34 can be found in the specification, *e.g.*, at page 4, lines 5-10; page 8, lines 7-14; page 9, lines 25-26; page 16, lines 18-22; and in original claims 1-3, 8 and 9.

The powder inhaler of **independent claim 35** includes a dosing unit for providing a dose of powder and a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder in use is drawn on inhalation by a user. The powder inhaler is characterized in that the inhaler further comprises a scraper which is movable relative to at least one of the surfaces of the flow path and is configured, on movement of the scraper relative to at least one of the surfaces of the flow path, to contact at least one of the surfaces of the flow path such as to dislodge powder accumulated on the surface. Support for independent claim 35 can be found in the specification, *e.g.*, at page 4, lines 5-10; page 8, lines 7-14; page 9, lines 25-26; page 16, lines 18-22; and in original claims 1-3, 8 and 9.

**(vi) Grounds of Rejection to be Reviewed on Appeal**

Claims 34-41 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Wetterlin (U.S. 4,524,769) or Hallworth *et al.* (U.S. 3,858,583).

Claims 55, 57-59, 61, and 62 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Wetterlin (U.S. 4,524,769) or Hallworth *et al.* (U.S. 3,858,583) in view of Ambrosio *et al.* (U.S. 5,829,434).

Claims 56 and 60 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Wetterlin (U.S. 4,524,769), Hallworth *et al.* (U.S. 3,858,583) and Ambrosio *et al.* (U.S. 5,829,434) in view of Andersson *et al.* (U.S. 6,257,232).

Claims 63 and 64 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentably obvious over Wetterlin (U.S. 4,524,769) and Hallworth *et al.* (U.S. 3,858,583) in view of Ambrosio *et al.* (U.S. 5,829,434) and further in view of Wetterlin (U.S. 5,983,893).

Claims 34-41 are rejected under the judicially created doctrine of obviousness-type double-patenting as being unpatentable over claims 1-4, 18, 23, 30, and 39 of Andersson *et al.* (U.S. 6,257,232).

Claims 55 and 59-61 are rejected under the judicially created doctrine of obviousness-type double-patenting as being unpatentable over claims 1-4 of Virtanen (U.S. 6,446,626) in view of Ambrosio *et al.* (U.S. 5,829,434).

**(vii) Argument**

I. Rejection of claims 34-41 as being anticipated by Wetterlin (U.S. 4,524,769) and Hallworth *et al.* (U.S. 3,858,583).

Appellants' claim 34 requires, *inter alia*, that the inhaler include a powder dislodging member which is of fixed position relative to one of the at least one or at least one other of the surfaces of the flow path and is configured, on relative movement of the at least one and one other of the surfaces of the flow path, to contact the other of the at least one or at least one other of the surfaces of the flow path so as to dislodge powder accumulated thereon. Claim 35 requires a scraper which is movable relative to at least one of the surfaces of the flow path and is configured, on movement thereof relative to the at least one of the surfaces of the flow path, to contact the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon. It is clear from Appellants' disclosure that these descriptions refer to powder accumulated on the surface from a previous inhaled dose so as to minimize dosage variations between doses. See, e.g., Appellants' specification at page 4, lines 21-25.

Wetterlin teaches an inhaler with "a rotating means 3" intended for disrupting aggregate particles of an active compound. See, e.g., Wetterlin at col. 2, lines 65-68. Wetterlin does not disclose that the "rotating means 3" is or includes a "powder dislodging member" as required by

pending independent claim 34, or a scraper as required by independent claim 35. Instead, the rotating means 3 (characterized by the Examiner as a powder dislodging member) is positioned only to break up particle agglomerates that are passing through the inhaler during inhalation by a user. See, e.g., Wetterlin at col. 3, lines 4-9.

The Examiner characterizes Wetterlin as describing a “powder-dislodging member 3, which is of fixed position relative to at least one of the surfaces of the flow path and is configured on relative movement of one and one other of the surfaces of the flow path in order to contact a surface of the flow path such as to dislodge powder accumulated thereon, wherein the powder dislodging member 3 comprises a scraper.” Office Action dated November 28, 2005, at page 3. See also, Advisory Action dated November 1, 2006, at page 2. Appellants disagree with this characterization of the Wetterlin’s disclosure for several reasons.

First, there is no teaching or suggestion in Wetterlin that the rotating means 3 can dislodge powder that has accumulated on a surface of the flow path during a prior inhalation. In the Advisory Action, the Examiner appears to take the position that the rotating means can prevent accumulation of powder on itself during its rotation. There is no indication in Wetterlin that this is the case, and even if it were this would not meet the requirement of claims 34 and 35 that the powder dislodgement member or scraper contact one of the surfaces of the flow path so as to dislodge powder accumulated thereon. The rotating means 3 cannot contact one of the surfaces of the flow path, as required by Appellants’ claims 34 and 35. The rotating means 3 is not positioned to contact any surface of the flow path. Instead, as shown in Figure 1 of Wetterlin, the rotating means 3 extends freely into the interior of the inhaler and does not contact any surface of the inhaler at any time. Powder dislodgment is not the intended function of the rotating means 3, nor would the rotating means 3 perform this function.

Second, contrary to the Examiner’s assertion, there is no teaching in Wetterlin of an inhaler that includes a powder dislodging member which is of fixed position relative to one of at least one or at least one other of the surfaces of the flow path of the inhaler. The rotating means 3 is configured to rotate relative to the surfaces of the flow path.

Thus, Wetterlin *et al.* does not teach the limitations of claims 34 and 45, and accordingly does not anticipate the claims.

Neither does Hallworth disclose a powder dislodging member or scraper as claimed by Appellants.

The Examiner asserts that rotor 5 of the Hallworth inhalation device is a powder dislodging member. Appellants disagree. Hallworth *et al.* discloses that the rotor 5 is a "free-running multi-bladed wheel mounted on a central spindle." Hallworth at col. 1, lines 58-60. "The rotor 5 is so positioned with respect to its spindle 6 and the end wall 3 that it brushes lightly against the end" of a hard gelatin capsule 13 containing a powdered medicament. Hallworth at col. 2, lines 21-23. "The rotation of the rotor therefore causes the capsule 13 to vibrate and this assists in the emptying of the cohesive powders from the capsule and the dispersion of such powders." Hallworth at col. 2, lines 24-27. "The rotation of the rotor 5 and the turbulent air flow within the dispersion chamber 2 will cause the efficient dispersion of the powdered medicament into the air being inhaled by the patient." Hallworth at col. 2, lines 61-65.

The rotor 5 disclosed by Hallworth is not a powder dislodging member. Like the rotating means 3 disclosed by Wetterlin and discussed above, the rotor 5 does not contact a surface of the flow path so as to "dislodge powder accumulated thereon" as required by Appellants' claims (see pending claims 34 and 35). The Examiner asserts that, because the rotor 5 is positioned to brush the end of capsule 13, "the rotor is capable of dislodging powder accumulated in the inhaler." Office Action dated May 15, 2006 (hereafter the "May 15<sup>th</sup> Office Action"), at page 5. However, Appellants maintain that rotor 5 is configured solely for the efficient dispersion of the powdered medicament during inhalation, by, for example, causing vibration of the capsule and consequent dispersion of the powder. See, e.g., Hallworth at col. 2, lines 25-28. As stated above, it is clear from Appellants' disclosure that the powder dislodging member dislodges powder accumulated on a surface of the flow path from a previous inhaled dose. See, e.g., Appellants' specification at page 4, lines 21-25. In contrast, there is no teaching or even a suggestion that the rotor 5 of Hallworth dislodges powder that has accumulated on the capsule due to previous inhalations. The rotor 5 merely serves to disperse the medicament that is being released from the capsule during the present inhalation.

Moreover, the rotor 5 is not "of fixed position" relative to a surface of the flow path, as required by claims 34 and 35, but instead is a "free-running wheel" that rotates freely within the flow path.

In view of the above remarks, neither Wetterlin nor Hallworth teaches or suggests a powder dislodging member, *i.e.*, a member capable of contacting a surface of the flow path to dislodge powder that has accumulated on a surface of the inhaler. Appellants therefore respectfully request that the rejections under 35 U.S.C. § 102(b) be withdrawn.

## II. Rejections under 35 U.S.C. § 103(a)

A. Rejection of claims 55, 57-59, 61, and 62 as being unpatentably obvious over Wetterlin (U.S. 4,524,769) and Hallworth *et al.* (U.S. 3,858,583) in view of Ambrosio *et al.* (U.S. 5,829,434).

Claims 55, 57-59, 61 and 62 depend from claim 34. None of the references, whether taken alone or in any proper combination, teach or suggest Appellants' invention as featured in claim 34. Ambrosio *et al.* is cited only for its disclosure of an inhalation device that has a powder housing means that includes helical threads and a cap for covering at least the housing. See, e.g., Ambrosio at col. 6, lines 17-35, and May 15<sup>th</sup> Office Action at page 7. Ambrosio does not supply that which is lacking in the primary references, as discussed above. Thus, even if the teachings of Ambrosio could be properly combined with those of Wetterlin and/or Hallworth, which is not conceded, such a combination would not have suggested the inhaler recited in Appellants' claim 34.

Claims 55, 57-59, 61, and 62, which depend from claim 34, are therefore not unpatentably obvious over the cited references.

B. Rejection of claims 56 and 60 as allegedly being unpatentably obvious over Wetterlin (U.S. 4,524,769), Hallworth *et al.* (U.S. 3,858,583) and Ambrosio *et al.* (U.S. 5,829,434) in view of Andersson *et al.* (U.S. 6,257,232).

Claims 56 and 60 ultimately depend from claim 34, which is discussed above. Andersson does not supply a teaching or suggestion of the features that are lacking in Wetterlin, Hallworth and Ambrosio as discussed above. Claims 56 and 60 are therefore patentable for at least the reasons discussed above.

C. Rejection of claims 63 and 64 as being unpatentably obvious over Wetterlin (U.S. 4,524,769) and Hallworth *et al.* (U.S. 3,858,583) in view of Ambrosio *et al.* (U.S. 5,829,434) and further in view of Wetterlin (U.S. 5,983,893).

Claims 63 and 64 ultimately depend from claim 34. Wetterlin (U.S. 5,983,893) does not supply a teaching or suggestion of the features that are lacking in Wetterlin, Hallworth and Ambrosio as discussed above. Claims 63 and 64 are therefore patentable at least for the reasons discussed above.

III. Rejections under the judicially created doctrine of obviousness-type double-patenting

The analysis employed in an obviousness-type double-patenting determination parallels the guidelines for a 35 U.S.C. § 103(a) rejection, and thus the factual inquiries set forth in Graham v. John Deere Co., 383 US 1, 148 USPQ 459 (1966) are applied. These factual inquiries are summarized as follows: (A) determine the scope and content of a patent claim in the application at issue; (B) determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue; (C) determine the level of ordinary skill in the pertinent art; and (D) evaluate any objective indicia of nonobviousness. Any obviousness-type double patenting rejection should make clear: (A) the differences between the inventions defined by the conflicting claims—a claim in the patent compared to a claim in the application; and (B) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is anticipated by, or would have been an obvious variation of the invention defined in a claim in the patent. MPEP 804(II)(B)(1). Furthermore, when considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. Id. citing General Foods Corp. v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1849 (Fed. Cir. 1992). However, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. MPEP 804(II)(B)(1) citing In re Vogel, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970).

A. Rejection of claims 34-41 as being unpatentable over claims 1-4, 18, 23, 30, and 39 of Andersson *et al.* (U.S. 6,257,232).

The claims of Andersson *et al.* (hereafter, the '232 patent) are directed to a powder inhaler having a movable member that inhibits accumulation of powder on a surface of the flow path downstream of the dosing means. See, Andersson *et al.* at claims 1, 4 and 23. The patent specification discloses how the movable member can inhibit accumulation of powder on a surface of the flow path, *e.g.*, by interrupting the stream of air flowing through the inhaler. See, e.g., Andersson *et al.* at col. 7 lines 19-35. The Examiner, at page 2 of the Advisory Action, describes the inhibition of powder accumulation as follows:

The inhibition of accumulation of powder, as stated in U.S. 6,257,232, can effectively be said to be dislodging already accumulated powder. The dictionary defines dislodge to mean to force out of a secure or settled position. Surely, if accumulation of powder is inhibited, it would be forcing out the powder, which is in a secured or settled position by virtue of being accumulated. There are many ways something can be inhibited.

Appellants concede that Andersson *et al.* describes an inhaler that prevents accumulation of powder. However, the patent does not describe or suggest an inhaler having the features of independent claims 34 or 35 of the pending application. The specification of Andersson *et al.* discloses how the movable member of the claims can inhibit accumulation of powder on a surface, *e.g.*, by the indirect flow path created by angled arms of a rotating disc, from centrifugal force developed by the rotation of the disc, or by recesses and projections on the undersurface of flanges of the disc, which provide enhanced turbulent flow adjacent the undersurface. Andersson *et al.* at col. 7, lines 17-35; and col. 8, lines 40-48. The specification of Andersson *et al.* does not support a movable member that is in a fixed position relative to a surface in the flow path and which is configured on relative movement of the surface and at least one other of the surfaces of the flow path to contact the other surface or at least one other of the surfaces of the flow path such as to dislodge powder accumulated on the surface. The specification of Andersson *et al.* also does not support a movable member that can be a scraper or a brush. Thus the claims of Andersson *et al.* do not anticipate or even suggest the subject matter of the pending



claims. Appellants therefore respectfully request withdrawal of the nonstatutory double patenting rejection as applied to pending claims 34-41.

B. Rejection of claims 55 and 59-61 as being unpatentable over claims 1-4 of Virtanen (U.S. Patent No. 6,446,626) in view of Ambrosio *et al.* (U.S. 5,829,434).

Neither Virtanen nor Ambrosio *et al.* describe or suggest a powder inhaler having the features of claims 55 and 59-61, at least because the claims of these patents, alone or in combination, do not teach or suggest the invention of claim 34 (from which claims 55 and 59-61 depend). There is no teaching or suggestion whatsoever in claims 1-4 of the Virtanen patent, or in any of the claims of Ambrosio *et al.*, of an inhaler having a powder dislodging member, which is a scraper or a brush, in fixed position relative to at least one other of the surface of the flow path configured on relative movement of the surface of the flow path, to contact the other of the at least one or at least one other of the surfaces of the flow path such as to dislodge powder accumulate on the surface. Appellants therefore respectfully request withdrawal of the nonstatutory obviousness-type double patenting rejection as applied to pending claims 55 and 59-61.

CONCLUSION

For the reasons set forth above, Appellants respectfully request that the rejections of claims 34-41 and 55-64 be withdrawn.

An attached Claims Appendix (viii) contains a copy of the claims under appeal.

An Evidence Appendix (ix) and a Related Proceedings Appendix (x) are attached as required, but neither contains any subject matter.

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Enclosed is a Petition for Extension of Time for one month. Please apply the petition fee of \$120, the appeal brief fee of \$500 (as required under 37 C.F.R. § 41.20(b)(2)) and any other necessary charges, or any credits, to Deposit Account No. 06-1050, referencing Attorney Docket No. 06275-131002.

Respectfully submitted,

Date: February 9, 2007 .....

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**(viii) Claims Appendix**

34. A powder inhaler for administering powder by inhalation, comprising:  
a dosing unit for providing a dose of powder; and  
a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user;  
characterized in that at least one of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path and in that the inhaler further comprises a powder dislodging member which is of fixed position relative to one of the at least one or at least one other of the surfaces of the flow path and is configured on relative movement of the at least one and one other of the surfaces of the flow path, to contact the other of the at least one or at least one other of the surfaces of the flow path such as to dislodge powder accumulated thereon,  
wherein the powder dislodging member comprises one of a scraper or a brush.
35. A powder inhaler for administering powder by inhalation comprising:  
a dosing unit for providing a dose of powder; and  
a flow path downstream of the dosing unit which is defined by a plurality of surfaces through which a stream of air entraining the dose of powder is in use drawn on inhalation by a user;  
characterized in that the inhaler further comprises a scraper which is movable relative to at least one of the surfaces of the flow path and is configured, on movement thereof relative to the at least one of the surfaces of the flow path, to contact the at least one of the surfaces of the flow path such as to dislodge powder accumulated thereon.
36. The inhaler according to claim 35, wherein the at least one of the surfaces of the flow path is movable relative to at least one other of the surfaces of the flow path and the scraper is of fixed position relative to the at least one other of the surfaces of the flow path.

37. The inhaler according to claim 35, wherein the flow path includes a chamber which includes an inlet and an outlet.

38. The inhaler according to claim 37, wherein the at least one of the surfaces of the flow path defines at least part of the chamber.

39. The inhaler according to claim 38, wherein the at least one and the at least one other of the surfaces of the flow path define at least in part opposed surfaces of the chamber and include the inlet and the outlet thereto.

40. The inhaler according to claim 39, further comprising a storage chamber for storing a plurality of doses of powder, which storage chamber includes a filling inlet in one of the opposed surfaces of the chamber, and a plug for sealing the filling inlet of the storage chamber, which plug includes the scraper.

41. The inhaler according to claim 35, further comprising a mouthpiece which includes one of the at least one or at least one other of the surfaces of the flow path.

55. A powder inhaler according to claim 34, further comprising  
a housing which includes a screw thread;  
a mouthpiece which is attached to the housing, wherein at least one part of the mouthpiece is rotatable relative to the housing and includes the at least one of the surfaces of the flow path; and

a cap for covering at least the mouthpiece, which cap includes a screw thread for engaging the screw thread on the housing;

wherein the mouthpiece and the cap are configured such that at least part of the mouthpiece is rotated relative to the housing on one of screwing or unscrewing the cap; characterized in that the at least part of the mouthpiece remains substantially in fixed position relative to the housing on the other of screwing or unscrewing the cap.

56. The inhaler according to claim 55, wherein at least one other of the surfaces of the flow path is of fixed position relative to the housing such that the at least one of the surfaces of the flow path is moved relative to the at least one other of the surfaces of the flow path on rotation of the at least part of the mouthpiece relative to the housing.

57. The inhaler according to claim 55, wherein the mouthpiece and the cap each include parts which engage on the one of screwing or unscrewing the cap so as to rotate the at least part of the mouthpiece relative to the housing.

58. The inhaler according to claim 57, wherein the engaging parts comprise at least one resiliently-biased member and at least one projection or recess, which at least one resiliently-biased member is configured to engage the at least one projection or recess on the one of screwing or unscrewing the cap.

59. The inhaler according to claim 55, wherein the at least part of the mouthpiece is rotated relative to the housing on unscrewing the cap.

60. The inhaler according to claim 55, wherein the housing includes a rotatable grip portion which in use is rotated to provide a dose of powder of inhalation, which grip portion is rotated to provide a dose of powder for inhalation in the same sense as that in which the cap is rotated to rotate the at least part of the mouthpiece relative to the housing.

61. The inhaler according to claim 55, further comprising a rotation resistance mechanism for providing resistance to relative rotation of the least part of the mouthpiece and the housing.

62. The inhaler according to claim 61, wherein the rotation resistance mechanism is configured so as to allow rotation of the mouthpiece relative to the housing on the other of

screwing or unscrewing the cap only for forces greater than that required to rotate the cap on the one of screwing or unscrewing the cap.

63. The inhaler according to claim 62, wherein the rotation resistance mechanism comprises a ratchet mechanism.

64. The inhaler according to claim 62, wherein the inhaler is configured such that rotation of the at least part of the mouthpiece relative to the housing on the other of screwing or unscrewing the cap causes no damage thereto.

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**(ix) Evidence Appendix**

None

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**(x) Related Proceedings Appendix**

None.